

Registration No 88867-2

Material Sent for Data Extraction

Reg. # 88867-2

Description: Reg

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 6/6/13

☐ Notification Dated _____

☒ New CSF(s) Dated 2/21/12

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jennifer Urbanski

Phone: 347-0156 Division: RD

Date: 6/6/13



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Chemical Safety and Pollution Prevention
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

88867-2

Date of Issuance:

JUN 06 2013

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Protector 2F

Name and Address of Registrant (include ZIP Code):

Willapa-Grays Harbor Oyster Growers Association
P.O. Box 3, Ocean Park, WA 98640

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(a). You must:

1. Submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Submit or cite any data which have previously been required for imidacloprid.
3. Make the following label change before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No 88867-2."

Signature of Approving Official:

John Hebert, Product Manager 07
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

JUN 06 2013

EPA Form 8570-6

4. Note that monitoring data reporting is required under the National Pollutant Discharge Elimination System (NPDES) permit. We request that you submit this information to the Registration Division, Office of Pesticide Programs, as well.

5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the CSF currently on file for this product is the basic CSF, dated 2/21/12.

If you have any questions, please contact Dr. Jennifer Urbanski at 703-347-0156 or urbanski.jennifer@epa.gov.

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

GROUP **4A** INSECTICIDE

PROTECTOR 2F

**FOR USE ONLY IN WILLAPA BAY/ GRAYS HARBOR, WASHINGTON,
TO CONTROL BURROWING SHRIMP IN COMMERCIAL SHELLFISH
BEDS**

ACTIVE INGREDIENT:

Imidacloprid: 1-[(6-Chloro-3-pyridiny)methyl]-N-nitro-2-imidazolidinimine..... 21.4%

OTHER INGREDIENTS:..... 78.6%

TOTAL:.....100.0%

Contains 2 pounds of imidacloprid per gallon.

KEEP OUT OF REACH OF CHILDREN CAUTION-CAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No.

EPA Establishment No.

SHAKE WELL BEFORE USING

**ACCEPTED
JUN 06 2013**

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**

EPA. Reg. No: 88867-2

FIRST AID	
If swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information</p> <p>NOTE TO PHYSICIAN</p> <p>No specific antidote is available. Treat the patient symptomatically.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Harmful if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton
- Shoes and socks
- Protective eyewear

Follow Manufacturer's instructions for cleaning/maintaining PPE. If instructions for washables do not exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS STATEMENTS

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users Must:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Wash contaminated area thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops and weeds. Do not allow this product to drift to blooming crops or weeds are visiting the treatment area. This product is toxic to wildlife and highly toxic to aquatic invertebrates.

DIRECTIONS FOR USE

It is a violation of the Federal law to use this product in a manner inconsistent with its labeling. A copy of this label must be in the possession of the user at the time the product is applied.

READ THIS LABEL: Read the entire label and follow all use directions and precautions.

For use only to control burrowing shrimp in intertidal commercial shellfish beds of Washington State's Willapa Bay and Grays Harbor.

MIXING INSTRUCTIONS:

To prepare the application mixture, add a portion of the required amount of water to the spray tank, begin agitation, and add the Protector 2F. Complete filling tank with the balance of water needed. Be sure to maintain agitation during both mixing and application.

Do NOT formulate this product into other end-use products.

APPLICATION INSTRUCTIONS:

To control burrowing shrimp in intertidal commercial shellfish beds [of Washington State's Willapa Bay and Grays Harbor], apply at a maximum rate of 0.5 lb a.i. imidacloprid /acre per year using the following properly calibrated application equipment:

- Helicopters equipped with boom $\frac{3}{4}$ as long as rotor diameter equipped with Accuflo or similar nozzles
- Backpack sprayer.
- Ground based vehicle with boom.

RESTRICTIONS:

- Do not harvest shellfish within thirty days after treatment.
- All ground must be properly staked and flagged to protect adjacent shellfish and water areas. For aerial applications, the corners of each plot must be marked so the plot is visible from an altitude of at least 500ft.
- Aerial applications must be on beds exposed at low tide.
- A single application of imidacloprid per year is allowed.
- No adjuvants or surfactants are allowed with the use of this product.
- All applications must occur between April 15 and December 15.
- A 100-foot buffer zone must be maintained between the treatment area and the nearest shellfish to be harvested when treatment is by aerial spray; a 25 foot buffer zone is required if treatment is by hand spray.
- Do not apply aerially during Federal holiday weekends. During aerial applications, all public access areas within one-quarter (1/4) mile and all public boat launches within a quarter (1/4) mile radius of any bed scheduled for treatment shall be posted. Public access areas shall be posted at 500 foot intervals at those access areas more than 500 feet wide. Signs shall be a minimum of 8 1/2 x 11 inches in size, and be made of a durable

weather-resistant, white material. The sign will say "Imidacloprid will be applied for burrowing shrimp control on [date] on commercial shell fish beds. Do not Fish, Crab or Clam within one-quarter mile of the treated area. The location of the treated area will be included on the sign.

- The sign will include lettering shall be in bold black type with the word "WARNING" or "CAUTION" at least one-fourth (1/4) of an inch high. Signs shall be posted so they are secure from the normal effects of weather and water currents, but cause no damage to private property. Signs shall be posted at least 2 days prior to treatment and shall remain for at least 30 days after treatment.

SPRAY DRIFT MANAGEMENT:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determines the potential for spray drift. The applicator and the entity authorizing spraying are responsible for considering all these factors when making decisions.

To minimize spray drift, the applicator should be familiar with and take into account the following drift reduction advisory information. Additional information may be available from state enforcement agencies or the Cooperative Extension on the application of the product.

The best drift management strategy and most effective way to reduce drift potential are to apply large droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see WIND, TEMPERATURE AND HUMIDITY, and TEMPERATURE INVERSIONS).

CONTROLLING DROPLET SIZE

- Volume – Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure – Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of Nozzles – Use the minimum number of nozzles that provide uniform coverage.
- Nozzle Orientation – Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is recommended practice. Significant deflection from the horizontal will reduce droplet size and increase drift potential.
- Nozzle Type – Use a nozzle type that is designed for the intended application. With most nozzle types, narrow spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift. Do not use nozzles producing a mist droplet spray.

APPLICATION HEIGHT

Making applications at the lowest possible height (helicopter, ground driven spray boom) that is safe and practical reduces exposure of droplets to evaporation and wind. (ground) upwind. Swath adjustment distance should increase with increasing drift potential (higher wind, smaller droplets, etc.).

WIND

Drift potential is lowest between wind speeds of 3-10 mph. However, many factors, including droplet size and equipment type, determine drift potential at any given speed. Application should be avoided below 3 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE INVERSIONS

Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud, which can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

AERIAL APPLICATION METHODS AND EQUIPMENT HELICOPTERS ONLY

Water Volume: Use 2 or more gallons of water per acre. The actual minimum spray volume per acre is determined by the spray equipment used. Use adequate spray volume to provide accurate and uniform distribution of spray particles over the treated area and to avoid spray drift.

Managing spray drift from aerial applications: Applicators must follow these requirements to avoid off-target drift movement: 1) boom length – the distance of the outmost nozzles on the boom must not exceed $\frac{3}{4}$ the length of the rotor, 2) nozzle orientation – nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees, and 3) application height – without compromising helicopter safety, applications should be made at a height of 10 feet or less above the crop canopy or tallest plants. Applicators must follow the most restrictive use cautions to avoid drift hazards, including those found in this labeling as well as applicable state and local regulations and ordinances.

GROUND APPLICATION (BROADCAST)

Water Volume: Use 5 or more gallons of water per acre. The actual minimum spray volume per acre is determined by the spray equipment used. Use adequate spray volume to provide accurate and uniform distribution of spray particles over the treated area and to avoid spray drift.

Spray tank should have constant agitation to assure adequate mixing of product.

AERIAL APPLICATIONS

All precautions should be taken to minimize or eliminate spray drift. Helicopters can be used to apply PROTECTOR 2F; however, DO NOT make applications by helicopter unless appropriate buffer zones can be maintained to prevent spray drift out of the target area, or when spray drift as a result of helicopter application can be tolerated. Aerial equipment designed to minimize spray drift, such as a helicopter

equipped designed to minimize spray drift, such as a helicopter equipped with a Microfoil™ boom, Thru-Valve™ boom or raindrop nozzles, must be used and calibrated. Except when applying with a Microfoil boom, a drift control agent may be added at the recommended label rate. To avoid drift, applications should not be made during inversion conditions, when winds are gusty or any other conditions which allow drift. Side trimming is not recommended with PROTECTOR 2F unless death of treated tree can be tolerated.

GROUND APPLICATIONS

Low Volume

Use equipment calibrated to deliver 5 to 20 gallons of spray solution per acre.

For low volume, selected proper nozzles to avoid over-application. Proper application is critical to ensure desirable results.

Restrictions During Temperature Inversions

Because the potential for spray drift is high during temperature inversions, do NOT make air applications during temperature inversions.

Mixing and Loading Requirements

The use of a properly designed and maintained containment pad for mixing and loading of any pesticide into application equipment is recommended. If containment pad is not used, maintain a minimum distance of 25 feet between mixing and loading areas and potential surface to groundwater conduits such as field sumps, uncased well heads, sinkholes, or field drains.

container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

This product is registered by the Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of reach of children, preferably in a locked storage area. Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER DISPOSAL [HANDLING]:

For containers smaller than 5 gallons: Nonrefillable container: Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Nonrefillable Containers Larger than 5 Gallons: Nonrefillable

Urbanski, Jennifer

From: aschreib@centurytel.net
Sent: Wednesday, May 29, 2013 5:55 PM
To: Urbanski, Jennifer
Subject: Re: labels for 88867-R and -E
Attachments: Federal 2F Label Ver 9 May 29 2013.doc; Federal__0_5G_Label Ver 8 May 29 2013.doc

Jennifer,

We have made all requested changes except we cannot figure out what our EPA registration number is. I will contact someone at EPA first thing tomorrow and track it down; otherwise, every thing should be in proper order. Scroll down for some answers to your questions.

From: Urbanski, Jennifer
Sent: Wednesday, May 22, 2013 10:45 AM
To: aschreib@centurytel.net
Subject: labels for 88867-R and -E

Hi Alan, below are some required label revisions and a few clarifying questions. Can you please send me the revised labels by Tuesday? Thanks!

Jenn

88867-R

- 1) On page 1, delete "Not for sale.... Association" and replace with "For use only in Willapa Bay/Grays Harbor, WA, to control burrowing shrimp in commercial shellfish beds."
- 2) Please add in the EPA Establishment # and the company name and address.
- 3) On page 2 in the First Aid statements, if in eyes must be first. If on skin and clothing is not needed, but if you choose to keep it it must be underneath if in eyes.
- 4) On page 2 in the First Aid box, above Note to Physician, add "Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX [add in number here] for emergency medical treatment information."
- 5) On page 2 move "Hazards to Humans and Domestic Animals" below "Precautionary Statements".
- 6) On page 2 delete "when working in a non-ventilated space" from the PPE section.
- 7) Throughout the label, you reference oyster beds but you also mention other organisms, like clams. For clarity, change references from "oyster beds" to "commercial shellfish beds".
- 8) On page 2, "Application INSTRUCTIONS" is misspelled.
- 9) On page 2, change "...maximum rate of 0.5 lb a.i./acre of imidacloprid..." to read "...maximum rate of 0.5 lb a.i. imidacloprid/acre ..."
- 10) On page 2, change "Avoid the use of spreaders that would..." to read "Do not use spreaders that would..."
- 11) On page 2, change "All spreader equipment should be calibrated..." to read "All spreader equipment must be calibrated..."
- 12) On page 2, change "Do not harvest clams or oysters..." to read "Do not harvest shellfish..."
- 13) On page 2, please correct the following sentence (see bold addition): "Public access areas shall be posted at 500 feet intervals at those access areas more than 500 feet wide."
- 14) On page 3, as the PHI is 30 days, change "... shall remain for at least 3 days after treatment" to read "....shall remain for at least 30 days after treatment".
- 15) On page 3 in the Storage and Disposal section, after container disposal, add "non-refillable. Do not reuse or refill this container."

- 16) On page 3 in the Storage and Disposal section, add "Pesticide Storage:" before the last two paragraphs and move this section under the statement "DO not contaminate..."

88867-E

- 1) On page 1, delete "Not for sale.... Association" and replace with "For use only in Willapa Bay/Grays Harbor, WA, to control burrowing shrimp in commercial shellfish beds."
- 2) Please add in the EPA Establishment # and the company name and address.
- 3) On page 2 in the First Aid statements, if in eyes statement is not needed and you may delete it if you wish.
- 4) On page 2 in the First Aid box, above Note to Physician, add "Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX [add in number here] for emergency medical treatment information."
- 5) On page 2 move "Hazards to Humans and Domestic Animals" below "Precautionary Statements".
- 6) On page 2, delete the text in the Hazards to Humans section and replace with the following: "Harmful if swallowed. Harmful if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist."
- 7) On page 2 delete "when working in a non-ventilated space" from the PPE section.
- 8) Throughout the label, you reference oyster beds but you also mention other organisms, like clams. For clarity, change references from "oyster beds" to "commercial shellfish beds".
- 9) On page 2, change "...maximum rate of 0.5 lb a.i./acre of imidacloprid..." to read "...maximum rate of 0.5 lb a.i. imidacloprid/acre ..."
- 10) On page 2, change "Do not harvest clams or oysters..." to read "Do not harvest shellfish..."

Clarifying questions

- 1) Where did you get the Environmental Hazards language from? They differ between the two labels. Although this is supposed to be confidential, I doubt it is any big deal to EPA. [REDACTED] We took the language from their 2F and 0.5G label and copied it for our use. Somewhere along the way, someone at EPA asked us to make some changes.
- 2) Where did the spray drift language come from on each label? Is it on another label? Same story. It came off the Nufarm labels and we were asked to change it to this language.

Jennifer Urbanski, Ph.D., Biologist
Insecticide-Rodenticide Branch, S7221
Registration Division (7505P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
(703) 347-015

***Commercial/financial information may be
entitled to confidential treatment***

Urbanski, Jennifer

From: Jonathan Peterson [jpeterson@centurytel.net]
Sent: Tuesday, June 04, 2013 3:29 PM
To: Urbanski, Jennifer
Cc: Hebert, John
Subject: RE: Willapa-Grays Harbor Oyster Growers Association
Attachments: Federal__0_5G_Label Ver 8 May 29 2013_jmucomments 6.4.2013.doc; Federal 2F Label Ver 8 April 9 2012 6.4.2013.doc

Here are the cleaned up version, I must have clicked on something wrong, my apologizes. If you need anything else please let me know.

Jonathan Peterson
Assistant Administrator
Ag Development Group, Inc.
Schreiber & Sons
Ph: 509-266-4348
Fax: 509-266-4317

From: Urbanski, Jennifer [<mailto:urbanski.jennifer@epa.gov>]
Sent: Tuesday, June 04, 2013 12:20 PM
To: Jonathan Peterson
Cc: Hebert, John
Subject: RE: Willapa-Grays Harbor Oyster Growers Association

Hi Jonathan, the labels still aren't the clean versions (all blue/red underlined text should be converted to plain black text like you would see in a regular label and red strikeouts should be deleted). Can you please send these updated labels to both me and John Hebert? Thank you!

Jenn

From: Jonathan Peterson [<mailto:jpeterson@centurytel.net>]
Sent: Tuesday, June 04, 2013 2:04 PM
To: Urbanski, Jennifer
Subject: RE: Willapa-Grays Harbor Oyster Growers Association

Good morning Jennifer, here are the updated and cleaned up versions of the two documents you requested. If you need anything else, please let me know. Thank you.

Jonathan Peterson
Assistant Administrator
Ag Development Group, Inc.
Schreiber & Sons
Ph: 509-266-4348
Fax: 509-266-4317

From: Urbanski, Jennifer [<mailto:urbanski.jennifer@epa.gov>]
Sent: Tuesday, June 04, 2013 6:23 AM
To: Jonathan Peterson
Subject: RE: Willapa-Grays Harbor Oyster Growers Association

Also, you still need the EPA Establishment # placeholder on the 2F product, in addition to the company address.... Also, the address you have on the 0.5G label is not the same as the address on the registration application, which is P.O. box 3, Ocean Park, WA 98640. Which is correct? Be sure the correct one is on both labels.

From: Jonathan Peterson [<mailto:jpeterson@centurytel.net>]
Sent: Monday, June 03, 2013 12:03 PM
To: Urbanski, Jennifer
Subject: Willapa-Grays Harbor Oyster Growers Association

Jennifer, here is the latest changes for the two documents you requested. We are just waiting to hear back about the EPA establishment number. If you have any questions please let me know. Thank you.

Jonathan Peterson
Assistant Administrator
Ag Development Group, Inc.
Schreiber & Sons
Ph: 509-266-4348
Fax: 509-266-4317

3/25/13



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 88867-E	2. EPA Product Manager PM#	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Protector 2F		
5. Name and Address of Applicant (Include ZIP Code) Willapa-Grays Harbor Oyster Growers Association P.O. Box 3, Ocean Park, WA 98640 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 228-572 Product Name Imidacloprid 2F Insecticide/Nuprid 25C	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

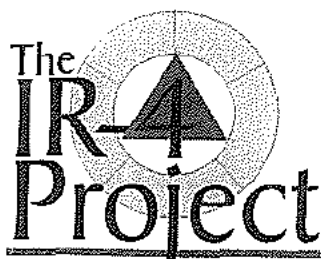
This is an application for a me-too registration and amendment to add control of burrowing shrimp and ghost shrimp in oyster beds in Willapa Bay and Grays Harbor, Washington, USA. IR-4 is filing a petition to support establishment of a tolerance in shellfish (no group name 99, Monograph Number 000).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper placed <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alan Schreiber	Title Designated Agent	Telephone No. (Include Area Code) 509-266-4348
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Designated Agent	
4. Typed Name Alan Schreiber	5. Date 2/1/2012	



Providing Safe and Effective Pest
Management Solutions for
Specialty Crop Growers

IR-4 Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540
732.932.9575
fax: 609.514.2612
ir4.rutgers.edu

February 7, 2012

Ms. Barbara Madden
EPA-OPP-Documents Processing (REGFEE)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

Dear Barbara:

RE: Imidacloprid
Protector 0.5G, EPA Registration No. pending
Protector 2F, EPA Registration No. pending
Imidacloprid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of imidacloprid (1-[6-chloro-3-pyridinyl] methyl)- *N*-nitro-2-imidazolidinimine) and its metabolites containing the 6-chloropyridinyl moiety, calculated as the stoichiometric equivalent of imidacloprid

New Uses:

Description	IR-4 PR No.	Source of New Tolerance
Fish-shellfish, mollusc	I0553	Volume 2
Fish	none	Volume 2 and approved waiver request for fish uptake and metabolism study

FEE CATEGORY: R170

REGISTRATION FEE: \$119,952 (See IR-4 Exemption Request below)

Electronic Submission to Follow

The undersigned, Dr. Keith Dorschner, Entomology Program Manager, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Station of Washington submits this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, imidacloprid (40 CFR 180.472).

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

List of Studies Submitted in Support of Proposed Tolerances for imidacloprid:

Vol. No.	Volume Title
2	Imidacloprid: Magnitude of the Residue on Oyster
3	IR-4 Minor Use Submission in Support of Tolerances for Imidacloprid In or On Fish and Shellfish (note: this is a volume of non-GLP studies and reports provided to IR-4 in support of the registration)

I request that this petition be reviewed under the Pesticide Registration Improvement Act and that EPA should exempt the registration fee for review of these uses.

The toxicological database for imidacloprid is complete, with the exception of an immunotoxicity study. The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system.

An immunotoxicity study is required as a part of new data requirements in 40 CFR Part 158 for conventional pesticide registration; however, the Agency does not believe that conducting a functional immunotoxicity study will result in a lower POD than that currently used for overall risk assessment. Therefore, a database uncertainty factor (UFDB) is not needed to account for lack of this study. EPA has determined that reliable data show the safety of infants and children would be adequately protected with a 1X FQPA SF for all exposure scenarios, except acute dietary (all populations).

A developmental neurotoxicity study was performed with imidacloprid and well-defined NOAELs were achieved in the study.

A fish uptake and metabolism study has not been performed for imidacloprid; however, a waiver has been submitted to EPA and approved. See Volume 3 for the waiver rationale. ChemSAC approval of the waiver is provided in Section G of the petition (Volume 1). A tolerance on fish is proposed in Section F of the petition. EPA may consider this tolerance request appropriate if there are concerns about inadvertent residues in fish as a result of oyster bed treatments.

I also submit the following in support of the proposed tolerances for imidacloprid:

1. Notice of Filing
2. EPA Form 8570-1 (Protector 0.5G)
3. EPA Form 8570-1 (Protector 2F)
4. EPA Form 8570-27 (Mallet 0.5G)
5. EPA Form 8570-27 (Imidacloprid 2F Insecticide/Nuprid 2SC)
6. EPA Form 8570-34 (Protector 0.5G)
7. EPA Form 8570-34 (Protector 2F)
8. EPA Form 8570-35 (Protector 0.5G) Agency and Public copies
9. EPA Form 8570-35 (Protector 2F) Agency and Public copies
10. Protector 2F draft label (5 copies)
11. Protector 0.5G draft label (5 copies)

The following non-GLP studies were provided to IR-4 in support of the registration. They are found in Volume 3.

1. Experimental Applications of Imidacloprid to Control Burrowing Shrimp at the Commercial Scale: 2008
2. Field Trials of Imidacloprid on Burrowing Shrimp, 2009
3. Rationale for Waiving the Need for a Fish Uptake and Metabolism Study
4. Toxicological Evaluation of Imidacloprid (as Imida E AG 2F) using Sheepshead Minnows
5. Assessing the Hazards of Imidacloprid to Non-Target Fishes
6. Development of a new method for the determination of residues of the neonicotinoid insecticide Imidacloprid in juvenile Chinook (*Oncorhynchus tshawytscha*) using ELISA detection
7. Final Report – December 2011 Non-Target Effects of Imidacloprid on Dungeness crab in Willapa Bay, Washington 2008 to 2011
8. Impact of imidacloprid on epi-benthic and benthic invertebrates: Initial studies to describe the Sediment Impact Zone (SIZ) related to imidacloprid treatments to manage burrowing shrimp
9. Impact of imidacloprid on epi-benthic and benthic invertebrates: Preliminary small plot studies, 2006-07
10. Studies on the non-target effects of imidacloprid on Dungeness crab in Willapa Bay, Washington
11. SUPPLEMENT Toxicological Evaluation of Imidacloprid (as Imida E AG 2F) Using Sheepshead Minnows – Draft Report submitted by Nautilus Environmental, LLC to the University of Washington
12. Ecological Risk Assessment of Imidacloprid Applications to Control Burrowing Shrimp in Oyster Beds of Willapa Bay and Grays Harbor, WA

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per



Keith Dorschner, Ph.D.
Entomology Program Manager
Rutgers, the State University of NJ
500 College Road East, Suite 201 W
Princeton, NJ 08540

cc: Alan Schreiber
RFC (transmittal letter, petition)



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1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Willapa-Grays Harbor Oyster Growers Assoc., P.O. Box 3, Ocean Park, WA 98640 (xxx-xxx-xxxx)	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date 2/1/2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Aquatic Food Crop	Product Name Protector 2F

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 2/1/2012	Typed or Printed Name and Title Alan Schreiber
---------------	------------------	---



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Willapa-Grays Harbor Oyster Growers Association P.O. Box 3 Ocean Park, WA 98640	EPA File Symbol/Registration Number 88867-E
	Product Name Protector 2F
	Date of Confidential Statement of Formula (EPA Form 8570-4) 2/21/12

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Imidacloprid

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid	[REDACTED]	
Product ingredient source information may be entitled to confidential treatment		
Signature 	Name and Title Alan Schreiber	Date 02/01/2012

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy



NUFARM AMERICAS, INC.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919-379-2515

August 31, 2012

Document Processing Desk (IR-4)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

**Subject: Letter of Authorization for Citation of Data- PROTECTOR 2F
Interregional Research Project No. 4 (IR-4)**

To whom it may concern:

Nufarm Americas Inc. (000228) hereby grants permission to IR-4 pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq., to cite Nufarm Americas Inc. data on file with the US EPA for NUPRID 2F, EPA Product Registration Number 228-484; and NUPRID 2SC, EPA Product Registration Number 228-572. NUPRID 2F (228-484) and NUPRID 2SC (228-572) are identical in composition.

Product Chemistry: 228-572 (NUPRID 2 F)

MRID#

- | | |
|----------|---|
| 47306301 | Houghton, R. (2007) Imidacloprid 2F: Product Chemistry Volume II: Product Identity and Composition, Description of Materials Used to Produce the Product, Description of the Formulation Process, and Discussion of Formation of Impurities. Project Number: RTP/07/105/REG. Unpublished study prepared by Nufarm Americas, Inc. 102 p. |
| 47306302 | Houghton, R. (2007) Imidacloprid 2F: Product Chemistry Volume III: Preliminary Analysis, Certified Limits, and Enforcement Analytical Methods. Project Number: RTP/07/105/REG. Unpublished study prepared by Nufarm Americas, Inc. 29 p. |
| 46719708 | Sannappa, H. (2005) pH of Aqueous Solution/Suspension of Imidacloprid 240SC. Project Number: 4370/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 26 p. |
| 46719709 | Anand, H. (2005) Viscosity of Imidacloprid 240SC. Project Number: 4371/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 33 p. |
| 46742001 | Anand, H. (2005) Physical State of Imidacloprid 240SC. Project Number: 4364/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 21 p. |
| 46742002 | Pardhasaradhi, V. (2005) Oxidation/Reduction (Chemical Incompatibility) of Imidacloprid 240SC. Project Number: 4365/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 23 p. |
| 46742003 | Anand, H. (2005) Flammability of Imidacloprid 240SC. Project Number: 4366/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 25 p. |
| 46742005 | Pardhasaradhi, V. (2005) Density of Imidacloprid 240SC. Project Number: 4372/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 24 p. |
| 47740301 | Gravelle, W. (2009) Storage Stability and Corrosion Characteristics: Imidacloprid 2F (NUP-07387): 12-Month Interim Report. Project Number: 24014, P800. Unpublished study prepared by Eurofins-Product Safety Laboratories. 30 p. |



Acute Toxicity: 228-484 (NUPRID 2F)

MRID#

46742006	Latha, M. (2005) Acute Oral Toxicity Study (Acute Toxic Class Method) with Imidacloprid 240SC in Wistar Rats. Project Number: 4325/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 34 p.
46742007	Latha, M. (2005) Acute Dermal Toxicity Study with Imidacloprid 240SC in Wistar Rats. Project Number: 4326/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 29 p.
46742008	Kumar, M. (2005) Acute Inhalation Toxicity Study with Imidacloprid 240SC in Wistar Rats. Project Number: 4327/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 43 p.
46742009	Yogeesh, B. (2005) Acute Eye Irritation/Corrosion Study with Imidacloprid 240SC in New Zealand White Rabbits. Project Number: 4329/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 44 p.
46742010	Yogeesh, B. (2005) Acute Dermal Irritation/Corrosion Study with Imidacloprid 240SC in New Zealand White Rabbits; Final Report. Project Number: 4328/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 38 p.
46742011	Venugopala, K. (2005) Skin Sensitization Study (Magnusson and Kligman Test) with Imidacloprid 240SC in Guinea Pigs. Project Number: 4330/05. Unpublished study prepared by Advinus Therapeutics Private Limited. 48 p.

RESTRICTIONS

1. This data citation authorization includes only the data listed above by MRID # submitted by Nufarm Americas Inc. for EPA Registration Number 228-484 and 228-572.
2. This data citation authorization is granted by Nufarm Americas Inc. in support of IR-4 registration of formulation(s) deemed by US EPA to be substantially similar to NUPRID 2F (228-484) and NUPRID 2SC (228-572).
3. This letter does not authorize IR-4 to extend such data citation permission to any third party.
4. All data authorized to be cited hereunder shall remain the property of Nufarm Americas Inc. and such data or data citation right shall not be transferred by IR-4 in any manner whatsoever without express prior written consent of Nufarm Americas Inc.

Should you have any questions please contact me at the address and telephone number above.

Regards,

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas, Inc.





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WASHINGTON, D.C. 20460

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DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867- E	Page 1 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640	Product Protector 2F	
Ingredient(s): Imidacloprid (PC Code 129099)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	SUBPART D: PRODUCT PROPERTIES TEST GUIDELINES				
	Series 61 & 62 Data Requirements				
830.1550 / 61-1	Product Identity and Composition	47306301	Nufarm Inc (000228)	PER	
830.1600 / 61-2	Description of the Materials Used to Produce the Product	47306301	Nufarm Inc (000228)	PER	
830.1820 / 61-2	Description of the Production Process	--	--	NR	Footnote 1
830.1650 / 61-2	Description of the Formulation Process	47306301	Nufarm Inc (000228)	PER	
830.1670 / 61-3	Discussion of the Formation of Impurities	47306301	Nufarm Inc (000228)	PER	
830.1700 / 62-1	Preliminary Analysis	--	--	NR	Footnote 2
830.1750 / 62-2	Certified Limits	47306302	Nufarm Inc (000228)	PER	
830.1800 / 62-3	Enforcement Analytical Method	47306302	Nufarm Inc (000228)	PER	
	Series 63 (Phys/Chem Properties) Data Requirements				
830.6302 / 63-2	Color	--	--	NR	Footnote 3
830.6303 / 63-3	Physical State	46742001	Nufarm Inc (000228)	PER	
830.6304 / 63-4	Odor	--	--	NR	Footnote 4
830.7200 / 63-5	Melting Point	--	--	NR	Footnote 5
830.7220 / 63-6	Boiling Point	--	--	NR	Footnote 6
830.7300 / 63-7	Density, Bulk Density, Specific Gravity	46742005	Nufarm Inc (000228)	PER	
830.7520	Particle Size	--	--	NR	Footnote 7
830.7840 / 63-8	Solubility	--	--	NR	Footnote 8
830.7950 / 63-9	Vapor Pressure	--	--	NR	Footnote 9

Signature

Name and Title:
Alan Schreiber, Designated Agent

Date
August 31, 2012



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DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867-	Page 2 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640		Product Protector 2F
Ingredient(s): imidacloprid (PC Code 129099)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	SUBPART D: PRODUCT PROPERTIES TEST GUIDELINES				
830.7370 / 63-10	Dissociation Constant	--	--	NR	Footnote 10
830.7570 / 63-11	Partition Coefficient	--	--	NR	Footnote 11
830.7000 / 63-12	pH	46719708	Nufarm Inc (000228)	PER	
830.7050	UV/Visible Absorption	--	--	NR	Footnote 12
830.6313 / 63-13	Stability to normal / elevated temperatures, metals and metal ions	--	--	NR	Footnote 13
830.6314 / 63-14	Oxidizing/Reducing Reaction	46742002	Nufarm Inc (000228)	PER	
830.6315 / 63-15	Flammability	46742003	Nufarm Inc (000228)	PER	
830.6316 / 63-16	Explosibility	46742003	Nufarm Inc (000228)	PER	
830.6317 / 63-17	Storage Stability	47740301	Nufarm Inc (000228)	PER	
830.7100 / 63-18	Viscosity	46719709	Nufarm Inc (000228)	PER	
830.6319 / 63-19	Miscibility	--	Nufarm Inc (000228)	NR	Footnote 14
830.6320 / 63-20	Corrosion Characteristics	47740301	Nufarm Inc (000228)	PER	
830.6321 / 63-21	Dielectric Breakdown Voltage	--	--	NR	Footnote 15

Signature 	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012
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DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867-	Page 3 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640	Product Protector 2F	
Ingredient(s): imidacloprid (PC Code 129099)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 830	SUBPART D: PRODUCT PROPERTIES TEST GUIDELINES				

FOOTNOTES

1. Protector 2F is produced by a simple batching process and not through an integrated system therefore 830.1650 data is provided in lieu of 830.1620 data.
2. Protector 2F does not consist solely of TGA1 and is not produced via an integrated system, therefore 830.1700 data are not required.
3. Color (830.6302) data are not required according to PR 92-5 since Protector 2F is an End use product and color is not expected to impact product performance.
4. Odor (830.6304) data are not required according to PR 92-5 since Protector 2F is an End use product and odor is not expected to impact product performance.
5. Melting Point (830.7200) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
6. Boiling Point (830.7220) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
7. Particle Size (830.7520) data are not required since Protector 2F is a liquid End use product 40 CFR §158.310(f)(23).
8. Solubility (830.7840) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
9. Vapor Pressure (830.7950) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
10. Dissociation Constant (830.7370) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
11. Partition Coefficient (830.7570) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
12. UV/Visible Absorption (830.7050) data are not required since Protector 2F is an End use product 40 CFR §158.310 (e).
13. Stability to normal / elevated temperatures, metals and metal ions (830.6313) data is not required since Protector 2F is an End use product 40 CFR §158.310 (e).
14. Miscibility (830.6319) data are not required since Protector 2F is not an emulsifiable liquid for dilution with petroleum solvents 40 CFR §158.310 (f)(16).
15. Dielectric Breakdown Voltage (830.6321) data are not required since Protector 2F is not for use around electrical equipment 40 CFR §158.310 (f)(17).

Signature 	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012
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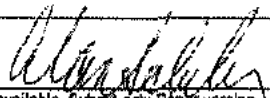
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DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867-	Page 4 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98840		Product Protector 2F
Ingredient(s): imidacloprid (PC Code 129099)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
SERIES 870	SUBPART F: HEALTH EFFECTS TEST GUIDELINES				
	Acute Toxicity Data Requirements				
870.1100 / 81-1	EP- Acute Oral Toxicity (RAT)	46742006	Nufarm Inc (000228)	PER	
870.1200 / 81-2	EP- Acute Dermal Toxicity	46742007	Nufarm Inc (000228)	PER	
870.1300 / 81-3	EP- Acute Inhalation Toxicity (waiver request)	46742008	Nufarm Inc (000228)	PER	
870.2400 / 81-4	EP- Primary Eye Irritation	46742009	Nufarm Inc (000228)	PER	
870.2500 / 81-5	EP- Primary Skin Irritation	46742010	Nufarm Inc (000228)	PER	
870.2600 / 81-6	EP- Skin Sensitization	46742011	Nufarm Inc (000228)	PER	

FOOTNOTES

Signature 	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012
--	---	-------------------------



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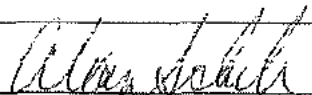
DATA MATRIX

Date August 31, 2012	EPA Reg. No./File Symbol 88867-	Page 5 of 5
Applicant's/Registrant's Name & Address: Willapa-Grays Harbor Oyster Growers Association, PO Box 3, Ocean Park, WA 98640	Product Protector 2F	
Ingredient(s): imidacloprid (PC Code 129099)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter (EPA CO#)	Status	Note
imidacloprid Generic Data Requirements					

Addressed via Formulators Exemption (40 CFR 152.85)

FOOTNOTES

Signature 	Name and Title: Alan Schreiber, Designated Agent	Date August 31, 2012
--	---	-------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 2/1/2012

EPA Reg No./File Symbol Company Number Pending

Page 1 of 1


Applicant's/Registrant's Name & Address

Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640

Product

Protector 2F

Ingredient Imidacloprid CAS No. 138261-41-3

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
1	Chemical Identity	47306301	228	PER	
2	Statement of Composition	47306301	228	PER	
3	Formation of Impurities	47306302	228	PER	
1	Preliminary Analysis	47306302	228	PER	
2	Certification of Limits	47306302	228	PER	
3	Analytical Method	47306302	228	PER	
17	Storage Stability	47740301	228	PER	
20	Corrosion Characteristics	47740301	228	PER	
1	Acute Oral Toxicity Rat	46742006	228	PER	
2	Acute Dermal Toxicity Rat/Rabbit	46742007	228	PER	
3	Acute Inhalation Rat	46742008	228	PER	
4	Primary Eye Irritation -- Rabbit	46742009	228	PER	
5	Primary Dermal Irritation -- Rabbit	46742010	228	PER	
6	Dermal Sensitization -- Guinea Pig	46742011	228	PER	
Signature 			Name and Title Alan Schreiber, Designated Agent		Date 02/01/2012




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 2/1/2012		EPA Reg No./File Symbol Company Number Pending		Page 1 of 1	
Applicant's/Registrant's Name & Address Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640		Product Protactor 2F			
Ingredient Imidacloprid CAS No. 138261-41-3					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		228		PER	
		228		PER	
		228		PER	
		228		PER	
		228		PER	
		228		PER	
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		228		PER	
		228		PER	
		228		PER	
		228		PER	
		228		PER	
Signature 			Name and Title Alan Schreiber, Designated Agent		Date 02/01/2012

DATA PACKAGE BEAN SHEET

Date: 27-Sep-2012

Page 1 of 1

Decision #: 461088

DP #: (405587)

PRIa

Parent DP #:

Submission #: 911548

E-Sub #:

*** Registration Information ***

Registration: 88867-E - PROTECTOR 2F

Company: 88867 - WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7913

Risk Manager Reviewer: Jennifer Urbanski JURBANSK

Sent Date: _____

PRIa Due Date: 06-Jun-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R170) NEW USE/EACH ADDITIONAL NEW FOOD USE;

Ingredients: 129099, Imidacloprid(21.4%)

R170
#31208

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 27-Sep-2012

Due Back: _____

DP Ingredient: 129099, Imidacloprid

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 08-Dec-2012

Team Name: CHEM

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attn PC reviewer: Please determine if the studies cited for PC support the registration of this product. The registrant claims that they are substantially similar to 228-572. I've included the label, data matrix, and csf. Please let me know if you need anything else, thanks!



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.:405587
PC Code(s): 129099

DECISION No.: 461088
EPA Reg. No. 88867-E

ACTION CODE: R170
FOOD USE: Yes

DATE: December 3, 2012

SUBJECT: Product Name: Protector 2F

FROM: Akiva Abramovitch, Ph. D.
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

J *SPB* 12-4-12

TO: Jennifer Urbanski/Venus Eagle, PM 01
Insecticide/Rodenticide Branch/RD (7505P)

Registrant Name: Willapa Grays Harbor Oyster Growers Association
Formulation Type: Liquid

INTRODUCTION:

The applicant requested a "me-too" registration of subject product claiming its similarity (identical) to Imidacloprid 2F Insecticide, EPA Reg. No. 228-572. In support of the application, the applicant cited product chemistry data of EPA Reg. No. 228-572 and provided an authorization letter from Nufarm to use their data. Also submitted a basic CSF dated February 21, 2012 and a proposed label.

FINDINGS:

1. The subject product was produced by a non-integrated formulation system, meaning that the active ingredient in the product is registered. The product contains 21.4% Imidacloprid Technical.
2. The subject product is identical in composition but not in labeling to the cited product EPA Reg. No. 228-572. Both products contain the same active ingredient at the same nominal concentration from an identical source, upper/lower certified limits for all the ingredients, and physical/chemical properties.

DP BARCODE No.:405587

DECISION No.: 461088

ACTION CODE: R170

PC Code(s): 129099

EPA Reg. No. 88867-E

FOOD USE: Yes

3. The label claim nominal concentrations of 21.4% Imidacloprid is consistent with that in the basic CSF, both are in compliance with the regulations of PR Notice 91-2.
4. A Since the label lists food uses the ingredients were approved for food uses under 40CFR 180.920

CONCLUSIONS:

1. From the product chemistry view point, the subject product is substantially similar in composition and labeling (% active ingredients) to EPA Reg. No. 228-572 but the label uses (food vs non-food and use pattern) are substantially different.
2. Based on the finding of 1. above, the TRB will have no objections for the use of the data from Imidacloprid 2F Insecticide, EPA Reg. No. 228-572 and for the "me-too" registration of the subject product.
3. The basic CSF dated February 21, 2012 is acceptable.
4. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.

DATA PACKAGE BEAN SHEET

Date: 27-Sep-2012

Page 1 of 1

Decision #: 461088

DP #: (405588)

PRIA

Parent DP #:

Submission #: 911548

E-Sub #:

*** Registration Information ***

Registration: 88867-E - PROTECTOR 2F

Company: 88867 - WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7913

Risk Manager Reviewer: Jennifer Urbanski JURBANSK

Sent Date: _____

PRIA Due Date: 06-Jun-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R170) NEW USE; EACH ADDITIONAL NEW FOOD USE;

Ingredients: 129099, Imidacloprid(21.4%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 27-Sep-2012

Due Back: _____

DP Ingredient: 129099, Imidacloprid

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 08-Dec-2012

Team Name: TOX

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Attn AT reviewer: Please determine if the studies cited for acute tox support the registration of this product. The registrant claims they are substantially similar to 228-572. I've included the label, CSF, and data matrix. Thanks!



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

**TECHNICAL REVIEW BRANCH
SIMILARITY DETERMINATION**

05/DEC/2012

MEMORANDUM

Subject: Name of Pesticide Product: Protector 2F
EPA Reg. No. /File Symbol: 88867-E
DP Barcode: D405588
Decision No: 461088
Action Code: R170
PC Codes: 129099 (imidacloprid)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew

12/14/12

To: Jennifer Urbanski, RM Team 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Applicant: Willapa-Grays Harbor Oyster Growers Association
P.O. Box 3
Ocean Park, WA 98640

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Imidacloprid	21.4
<u>Other Ingredients:</u>	<u>76.6</u>
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "Please determine if the studies for acute tox support the registration of this product. The registrant claims they are substantially similar to 228-572."

BACKGROUND: Willapa-Grays Harbor Oyster Growers Association has applied for registration of Protector 2F, EPA File Symbol 88867-E, claiming similarity to Nuprid 2SC Soil/Foliar Insecticide, EPA Reg. 228-572. Both products contain 21.4% imidacloprid. The submission includes a basic CSF dated February 28, 2012, a label, data matrix and company letter.

The data matrix cites acute toxicity studies with MRIDs 467420-06 to -11. A search of the OPP electronic databases shows that these studies were cited to support the registration of 228-572 in a prior TRB memo (Hashim; D348064; EPA File Symbol 228-LTE; 28/JAN/2008).

RECOMMENDATIONS:

1. TRB compared the basic CSFs of the proposed product, 88867-E, and the cited product, 228-572, and determined that the two formulations are toxicologically similar. The acute toxicity data referenced above may be used to support the proposed product. However, the two products are not similar in labeling.
2. The acute toxicity profile for the proposed product, Protector 2F, EPA File Symbol 88867-E, is as follows:

acute oral toxicity	III	cited	MRID 46742006
acute dermal toxicity	III	cited	MRID 46742007
acute inhalation toxicity	III	cited	MRID 46742008
primary eye irritation	IV	cited	MRID 46742009
primary skin irritation	IV	cited	MRID 46742010
dermal sensitization	negative	cited	MRID 46742011

3. The proposed basic CSF submitted for 88867-E must be reviewed and accepted by the TRB Product Chemistry Team.
4. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 088867-00002

PRODUCT NAME: Protector 2F

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

DATA PACKAGE BEAN SHEET

Date: 26-Mar-2012

Page 1 of 1

Decision #: 461088

DP #: (399882)

PRIA

Parent DP #:

Submission #: 911548

E-Sub #:

*** Registration Information ***

Registration: **88867-E - PROTECTOR 2F**

Company: 88867 - WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

Risk Manager: RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7913

Risk Manager Reviewer: Jennifer Urbanski JUBANSK

Sent Date: _____

Calculated Due Date: 06-Jun-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R170) NEW USE;EACH ADDITIONAL NEW FOOD USE;

Ingredients: 129099, Imidacloprid(21.4%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 15-Mar-2012

Due Back: _____

DP Ingredient: 129099, Imidacloprid

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: EFED / ERB5

Last Possible Science Due Date: 08-Dec-2012

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Attn reviewer: Please perform an ecological risk assessment for the use of imidacloprid on oyster beds to control burrowing shrimp. Joe Decant has been working on the EUP for the same use. Attached is the cover letter, label, and CSF. I also attached the label checklist--you'll note that there are a number of missing pieces. I have already contacted the registrant on these matters and he sent me a revised label which is attached. There were a few outstanding issues that he is looking into now. I noted these on the checklist and also included his email where he explains whether he has addressed each concern. I'll send the new information along when I receive it from the registrant. DP#399877 has also been beamed up and has the same use pattern. Thanks!



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: February 21, 2013

SUBJECT: IR4 Petition for the Use of Imidacloprid on Shellfish Beds in Willapa Bay and Grays Harbor, State of Washington
(PC Code 129099; DP Barcode D399685, 399877, 399882)

FROM: Joseph DeCant, Ecologist
Michael Barrett, Senior Chemist
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

THRU: Mah T. Shamim, Ph.D, Branch Chief
Environmental Risk Branch 5
Environmental Fate and Effects Division (7507P)

TO: Sidney Jackson, Risk Manager Reviewer
Barbara Madden, Minor Use Team Leader #05
Risk Integration, Minor Use and Emergency Response Branch
Registration Division (7505P)

The Environmental Fate and Effects Division (EFED) has completed its review of an IR4 new use petition for the use of imidacloprid (formulated as Protector 0.5G and Protector 2F) on shellfish beds at Willapa Bay and Grays Harbor in the state of Washington. Based upon a review of this new use and the labeled the maximum yearly use rate, the risks are outlined in **Table 1**.

Table 1. Summary of Environmental Risk Conclusions for Various Taxa Exposed to Imidacloprid for the Proposed Use on Shellfish Beds in Washington.	
Assessment Endpoint	Identified Concerns
Acute and Chronic Risk to Estuarine/marine Fish	None
Acute and Chronic Risk to Estuarine/Marine Invertebrates	Acute and Chronic on-site risk to free-swimming and benthic invertebrates; off-site acute risk to listed benthic invertebrates and chronic risk to benthic invertebrates due to flowable formulation
Aquatic Non-Vascular and Vascular Plants	None
Birds	Acute risk due to flowable formulation applied to exposed mudflats

Mammals	None
Concerns to Terrestrial Non-Target Insects	Concerns for invertebrates other than bees due to flowable formulation applied to exposed mudflats
Terrestrial Plants	None

Uncertainties and Additional Data Needs

There are a number of uncertainties that translate into data needs related to the proposed use of imidacloprid on shellfish beds in Willapa Bay and Grays Harbor. There is uncertainty related to actual exposure levels *in situ* at both on-site and off-site locations in pore water, sediments, and overlying water. Furthermore, while preliminary data have been submitted to the Agency regarding effects to the biotic community at on-site and off-site locations, additional data are needed to evaluate the potential for long-term effects to the biotic community. EFED anticipates that final reports for both the 2011 and 2012 seasons will be submitted to the Agency for review. These reports should include sampling of vegetation, pore water, sediment, overlying water, and biotic community metrics at on-site and off-site locations. In addition to these EUP data, additional monitoring of concentrations over time in Willapa Bay and Grays Harbor would also help to address the uncertainty related to the persistence of imidacloprid and possible long-term concentrations in sediments. This additional monitoring may be addressed through the NPDES permitting process with the State of Washington. The monitoring data collected as part of the NPDES program should then be submitted to the Agency for review. These reports and additional data would provide a basis for further evaluating the conclusions in this assessment and assist EFED to confirm or eliminate potential concerns from the risk conclusions identified in this assessment.

Another area of uncertainty relates to the degradates and their toxicity to fish. Current EcoSAR estimates of toxicity from EPISUITE poorly estimate toxicity levels of parent imidacloprid, and may therefore be providing poor estimates of the degradates as well. It appears that EPISUITE is underestimating the toxicity of the parent imidacloprid by two orders of magnitude. If this same margin of safety (two orders of magnitude) is applied to the degradates of concern, the desnitro olefin, desnitro (guanidine), and urea degradates remain a potential concern. At present EFED has not identified data on the desnitro olefin degradate and its rate of formation relative to the parent. Concerning the other two degradates, preliminary pore water data suggest that the urea and desnitro (guanidine) metabolites are likely forming. Monitoring data to be submitted from 2011 and 2012 EUP studies may address this uncertainty if levels of the chronic total residue levels in overlying water are undetectable. However, if the monitoring data reveal that these degradates form at relevant levels or if no data on these degradates are available, then additional toxicity information for these three degradates to saltwater fish would address this uncertainty. An acute toxicity test with sheepshead minnow (850.1075) using the appropriate degradates would provide an initial comparison with the parent compound. If the degradates appear to be more toxic than the parent compound, additional chronic testing (850.1400) may be warranted.

Note to file:

See jacket for 88867-R for ecological risk
assessment

and human health RA

21-Day Screen Completed by
Contractor

21-Day Expires on 3-2-12

Jacket # 88867-E
MRID# 487419

Content Screen: Recommend to Pass/**Fail**

11-3 Review: **Pass**/Fail/NA

Overall Status: Recommend to Pass/**Fail**

Transfer This Jacket to:

STEPHEN SCOTTABLE

(5)
399 877

NEW APPLICATIONS

DATE: 2/10/2012

FILE NUMBER: 88867-E

FEP (OPPIN ENTRY) LV FEB 13 2012
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ ASSIGN TO PM 51 (NO DATA)

 JACKET TO SHELF (DATA)

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 2-10-12 ^{3/23/09}
 Experts In-Processing Signature: B. R. Date 2-17-12 Fee Paid: Yes ☒
 Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>88867-E</u>		EPA Receipt Date: <u>2-10-12</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)		X		
	a) All inerts (link to http://www.epa.gov/oppr001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>inert?</u>	yes	no		
			X		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)		X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		X		
5	a) Selective Method (Fee category experts use)	yes	no		
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)		X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Studies associated with this submission (487419-MRID) initially had 2 pps illegible for study #02. Registrant was contacted through ph and email. Corrections were received on 02/23/2012.

Regarding the application package, Confidential statement of Formula was missing in the submission. Registrant was contacted on 02/17/2012 (the day jacket was received). Registrant sent the missing CSF on 02/22/2012. After reviewing it was found that CSF had previously registered product and Reg # in the CSF. Also, one of the inert that has purpose in formulation as [REDACTED] seems to have limit issue. However, it is unclear from the comments ^{whether the limit applies to both} [REDACTED] [REDACTED] Due to the delay in receiving the CSF and unclear comment we leave it to the PM to decide how to proceed if it is an issue of limit. Registrant sent rest of the corrections on 02/23/12. (Details in the email) ^{Limit question was referred to inerts branch 2/23 and as of due date no response was received.} PRN-11-3 review - Passed (Inerts NOT approved for food use under 40 CFR 180.920, preharvest application Jacket - Failed to growing crops

02-24-2012-JS

MRID-487419

* N/A - Not Applicable

Fixed by CSF
PM-7
OK!
2/28/12
JPH.

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Alan Schreiber / Amanda Bragg
Phone #: 509-266-4348
Email: aschreib@centurytel.net

Failed

First Call/Initials:

Date: 02-17-2012

Time: 9:14 am

Second Call/Initials:

Date: 02-22-2012

Time: 10:45 am

02-23-2012

1:45 pm

This is Srijana Shrestha, EPA contractor.

I'm calling regarding your submission in support of the product, Protector 2 F (EPA Reg # 88867-E) and Protector 0.54 (EPA Reg # 88867-R).

We have found the following deficiencies regarding:

PR Notice 2011-3: Yes or No

Volume/Study Title:

Study (2) for MRID-487419 had 2 pgs. illegible

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

Missing CSF, errors in CSF and AFES (details in pg. 3 and email)

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn:

Srijana Shrestha

Second Call/Email:

If we do not receive the corrections by 02/24/12, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



RE: Submission in support of products , "Protector 2F" (EPA Reg # 88867-E)
and "Protector 0.5G (EPA Reg# 88867-R)

Amanda Bragg to: Srijana Shrestha

02/23/2012 01:59 PM

4 attachments



EPA Form 8750-4 Protector 2F (2).jpg EPA Form 8750-4 Protector 2F.jpg EPA Form 8750-27 Protector 0.5G.jpg



EPA Form 8750-27 Protector 2F.jpg

Srijana,

I hope this is the last of the changes.

Thanks,

Amanda

-----Original Message-----

From: Srijana Shrestha [mailto:Shrestha.Srijana@epamail.epa.gov]

Sent: Wednesday, February 22, 2012 1:50 PM

To: Amanda Bragg; aschreib@centurytel.net

Cc: Sree Nair

Subject: Submission in support of products, "Protector 2F" (EPA Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Dear Ms. Bragg:

The second attachment still has the me too (previously registered product) as product name. Please edit it with correct product name. Also, regarding studies associated with this submission, Study(02) titled, "IR-4 Minor Use Submission in Support of Tolerances for Imidacloprid In or On Fish and Shell fish" has pgs 60 and 61 illegible. Please send revised legible pages or mark "BEST AVAILABLE COPY" if that is the case.

As I mentioned in our ph conversation, due to the time line we have, I will have to pass all the materials to the appropriate EPA Risk Manager on the 15th day i.e. 02/25/12 noon (Saturday). I will be out of office on 02/24/12 so, please send the corrections by 02/23/12 noon.

please direct all future contacts and correspondence after 02/25/12 to EPA Risk Manager. Feel free to call me back at 703-305-6471, if you have any questions.

Thanking you,
Srijana Shrestha
Macfadden, EPA Contractor
2777 S. Crystal Drive, S 4910 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060

From: "Amanda Bragg" <abragg@centurytel.net>
To: Srijana Shrestha/DC/USEPA/US@EPA
Date: 02/22/2012 04:02 PM
Subject: FW: Submission in support of products, "Protector 2F" (EPA
Reg # 88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Srijana,

Attached are the requested documents with the changes we discussed.
Please let me know if any of them are still illegible or if we need to make
any more changes.

Thank you,

Amanda Bragg
Assistant Administrator
Ag Development Group
Ph: 509-266-4348
Fax: 509-266-4317

From: Amanda Bragg [mailto:abragg@centurytel.net]
Sent: Wednesday, February 22, 2012 8:48 AM
To: 'Shrestha.Srijana@epamail.epa.gov'
Subject: FW: Submission in support of products, "Protector 2F" (EPA Reg #
88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

Srijana,

Attached please find the Confidential Statements of Formula for both
submissions.

Thank you,

Amanda Bragg
Assistant Administrator
Ag Development Group
Ph: 509-266-4348
Fax: 509-266-4317

From: Alan Schreiber [mailto:aschreib.as@gmail.com]
Sent: Tuesday, February 21, 2012 6:26 PM
To: Amanda Bragg
Subject: Fwd: Submission in support of products, "Protector 2F" (EPA Reg #
88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

----- Forwarded message -----

From: "Srijana Shrestha" <Shrestha.Srijana@epamail.epa.gov>
Date: Feb 17, 2012 10:32 AM
Subject: Submission in support of products, "Protector 2F" (EPA Reg #
88867-E) and "Protector 0.5G (EPA Reg# 88867-R)

To: <aschreib@centurytel.net>
Cc: "Sree Nair" <Nair.Sree@epamail.epa.gov>

Dear Mr. Schreiber:

This is regarding your submission in support of products, "Protector 2F" (EPA Reg # 888867-E) and "Protector 0.5G (EPA Reg# 88867-R). We have found following issue with your submission:

"Confidential Statement of Formula (EPA Form 8570-4)" is missing in both submissions.

Please send the missing form by email. Feel free to call me back at 703-305-6471, if you have any questions. I will be happy to assist you in anyway.

Thanking you,
Srijana Shrestha
Macfadden, EPA Contractor
2777 S. Crystal Drive, S 4910 A
Arlington, VA 22202
Ph: 703-305-6471
Fax: 703-305-5060 (See attached file: EPA Form 8750-4 Protector 0.5G.jpg)
(See attached file: EPA Form 8750-4 Protector 2F (2).jpg) (See attached
file: EPA Form 8750-4 Protector 2F.jpg)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 16, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-461088
EPA File Symbol or Registration Number: 88867-E
Product Name: PROTECTOR 2F
EPA Receipt Date: 10-Feb-2012
EPA Company Number: 88867
Company Name: WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION

ALAN SCHREIBER
WILLAPA-GRAYS HARBOR OYSTER GROWERS ASSOCIATION
P.O. BOX 3
OCEAN PARK, WA 98640

SUBJECT: Receipt of Registration Application and IR-4 Fee Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for registration and IR-4 fee waiver request. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R170
NEW USE;EACH ADDITIONAL NEW FOOD USE;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "m/She".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{911548:~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 5

Receipt No.

S- 911548

EPA File Symbol/Reg. No.

88867-E

Pin-Punch Date:

2/10/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R170

Granted: R170

Amount Due: \$ 0 184

Parent/Child Decisions:

88867+R S-911544

2E 7988 S-911542

~~Inert is not approved.~~ 1-5/02-24-12

☐ Inert Cleared for Intended Use

☒ Uncleared Inert in Product

Reviewer:

Date: 2/15/12

Remarks:

NO CSF INCLUDED

